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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,372	11/21/2003	Gary A. Dahl	310307.00005	3663

7590 04/20/2006

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EXAMINER
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HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/719,372

Applicant(s)

DAHL ET AL.

Examiner

Richard G. Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-171 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-171 are at issue and present for examination.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-45, 80-99, 108-144, drawn to a method of making an RNA product, classified in class 435, subclass 91.1.
- II. Claims 46-79, 107 and 149, drawn to a kit comprising a RNA polymerase and a promoter, classified in class 435, subclass 194.
- III. Claims 100-104, drawn to a method of attenuating expression of a target gene, classified in class 435, subclass 440.
- IV. Claims 105, 106, 145-148 drawn to an RNA or DNA product or host cell comprising said product, classified in class 536, subclass 23.1.
- V. Claims 150-171, drawn to a method for detecting an analyte in a sample, classified in class 435, subclass 15.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-IV and one of inventions (A)-(E).

- (A). SEQ ID NO: 1 or a sequence encoding SEQ ID NO: 2.
- (B). SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 4.
- (C). SEQ ID NO: 5 or a sequence encoding SEQ ID NO: 6.
- (D). SEQ ID NO: 7 or a sequence encoding SEQ ID NO: 8.

(E). SEQ ID NO: 14 or a sequence encoding SEQ ID NO: 15.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-IV and one of inventions (A)-(E).

(F). SEQ ID NO: 16

(G). SEQ ID NO: 19.

(H). SEQ ID NO: 27.

(I). SEQ ID NO: 28.

(G). SEQ ID NO: 29.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-IV and one of inventions (A)-(E).

(J). E. coli RNAP and promoter.

(K). T7 RNAP and promoter.

(L). T3 RNAP and promoter.

(M). SP6 RNAP and promoter.

It is acknowledged that many of the claims within groups I-V do not read on all of the above SEQ ID NOs:. The claims of each group will be examined to the extent that they read on the elected groups.

Claims 1-3, 13-46, 56, 68, 80-88, 98-130, 140-151 and 161-171 link(s) inventions I-V and A-M. The restriction requirement linking the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-3, 13-46, 56, 68, 80-88, 98-130, 140-151 and 161-171. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(M) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions II and IV are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the RNA polymerase of Group II and nucleic acid product of Group IV each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polymerase of Group II comprises amino acids and the nucleic acid of Groups IV comprises nucleic acids.

The invention of Group II and the Inventions of Groups I, III and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polymerase of Group II can be used synthesize an antibody.

Inventions IV and Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different

product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the RNA or DNA product can be made by chemical synthesis methods.

The product of Group IV is distinct from the methods of Groups III and V, as this product is neither made nor used by the methods of Groups III and V.

The methods of Groups I, III and V are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a horizontal line extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
4/10/2006